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EXAMINER	
COOK, CHRISTOPHER L	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@splglaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/823,793	ABUHAMAD, ALFRED Z.	
	Examiner	Art Unit	
	CHRISTOPHER COOK	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because it is virtually impossible to differentiate what is being disclosed in Figs 3-11. The quality is too poor and examiner maintains one of ordinary skill in the art would not readily recognize what is being illustrated. For example, all images look identical except for the actual shape of the displayed scan plane. Also, the "lead lines" are not clear. The "lead lines" generally refer to an entire plane without indicating specifically where the disclosed organ is in the plane. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7, 9-15 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the amended limitation to claim 1 which discloses a "tangible" computer readable medium is considered to be new matter. The specification is silent with respect to the specific limitation of "tangible".

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is rejected because the scope of the claim is unclear with respect to the limitation of "statistically based". The specific limitation of a "statistic" is not disclosed in the specification. Applicant has indicated that an example of such a statistic is the gestational age of a fetus; however, it is unclear as so

what other "statistics" the claim is referring to. As examiner noted before, any image plane could be "statistically based" from other image data.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 7 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al. "Nelson"*.

Regarding Claims 1-2, 7 and 14-20, *Nelson* discloses a system and a method implemented by a computer program product comprising instructions for enabling a computer to: acquire ultrasound data with a transducer for at least a portion of a body organ (fetal heart) (Page 1, "Introduction); generate and define at least one other plane with respect to a reference plane for the body organ based on specific data including spatial positions within the organ that define a relationship of the at least one other plane to the reference plane (Pages 4-5, "Fetal Cardiac Data Visualization") and to display automatically and substantially simultaneously, at least two ultrasound images corresponding to at least of the reference plane and data defining the at least one other plane (Fig. 5). It should be noted that the generated planes are defined by a spatial mathematical

relationship which relate the planes to one another by either a shift or rotation from the reference plane (i.e. 90^{o}).

As for Claims 3-4, *Nelson* discloses a reference plane as the four-chamber view and wherein the at least one other plane comprises data defining a ductal arch view (Fig. 5)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 5-6 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al. "Nelson"* in view of U.S. Patent No. 7,244,233 to *Krantz et al. "Krantz"*.

Regarding Claims 5-6 and 12, *Nelson* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for organs as described above. However, *Nelson* is silent with respect to the specific limitation of the organ being a fetal head. Further, *Nelson* is silent with respect acquiring ultrasound images for each of the sagittal, transverse, and coronal planes.

Krantz teaches from within the same field of endeavor with respect to ultrasound imaging of a fetus, a computerized method wherein the head of a fetus is imaged (Column 3, Line 62-Column 4, Line 5). Furthermore, *Krantz* teaches it is considered a well know expedient in the art to obtain ultrasound images of the sagittal, transverse and coronal planes which would include the biparietal diameter (Column 10, Lines 26-36).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program instructions as disclosed by *Nelson* to acquire and display ultrasound fetal head images acquired in the sagittal, transverse and coronal planes as described by *Krantz* in order to enhance and detect of fetal abnormalities using ultrasound.

With regard to Claim 13, Examiner contends the displaying disclosed by *Nelson* is displayed substantially in real time.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al.*

"Nelson" in view of U.S. Patent No. 7,244,233 to *Krantz et al. "Krantz"* as applied to claim 5 above, and further in view of U.S. Patent No. 6,306,089 to *Coleman et al. "Coleman".*

Regarding Claim 6, Nelson in view of *Krantz* disclose a computer program product program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. However, Nelson in view of *Krantz* are silent with respect to the specific limitation of wherein the reference plane is of the biparietal diameter.

Coleman teaches from within a similar field of endeavor with respect to fetal imaging wherein it is considered a well known expedient in the art to obtain an image plane to effectively measure the biparietal diameter of a fetus (Column 5, Lines 6-35).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the reference plane for imaging of a fetal organ as disclosed by *Nelson* in view of *Krantz* to include a reference plane which includes the biparietal diameter of the fetal head as described by *Coleman* in order to visualize vital organs of a fetus. Examine notes that such a modification requires nothing more than the mere combination of known prior art techniques when imaging the fetal head to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v.Teleflex Inc,* 82 USPQ2d 1385).

12. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al. "Nelson"* in view of U.S. Patent No. 6,290,648 to *Kamiyama et al. "Kamiyama"* in further view of *Applicants Admission* of the prior art.

Regarding Claims 9-11, *Nelson* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. *Nelson* is silent with respect to a computer program comprising image recognition software to facilitate the medical evaluation comprising steps to recognize a specific structure within an image, compare the structure with a reference image, and identify at least one of a normal and abnormal anatomical characteristic of the structure.

Kamiyama teaches an ultrasound diagnostic imaging apparatus (abstract) comprising image recognition software used to facilitate a medical evaluation (Column 7, Lines 58-67-Column 8, Lines 1-30). Furthermore, *Kamiyama* teaches wherein the software recognizes a specific structure within an image, compares the structure with a reference image, and identifies at least one of a normal and abnormal anatomical characteristic of the structure (Column 8, Lines 31-67).

Examiner further notes that Applicant has disclosed in the Specification, Paragraph [0067], "*One or more embodiments of the present invention can utilize, for example, standard (e.g. off-the-shelf) image recognition software to assess the level of the standardized planes and diagnose, or facilitate*

diagnosis...". Examiner notes that an "off-the-shelf" program is considered to be well known and commercially available prior to the claimed invention. Therefore, one of ordinary skill in the art would readily recognize a modification to include well known computer software program as disclosed by Applicant and *Kamiyama* to evaluate acquired image data.

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al. "Nelson"* in view of NPL "Sonography of the Normal Fetal Heart: A Practical Approach" to *Frates*.

Regarding Claim 21, *Nelson* discloses a computer program product comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. However, *Nelson* is silent with respect to obtaining image data corresponding to a number of gestational weeks. Examiner notes that it is considered a well known expedient in the art to correlate image acquisition of fetal organs with data such as gestational weeks as described by *Frates* (Fig. 11 A-D) since the fetus position changes during fetal development.

14. Claims 1, 7 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A

Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Counsil on Clinical Cardiology of the American Heart Association" to *Cerqueira et al.* *"Cerqueira"*.

Regarding Claims 1, 7 and 14-17, *Clark* discloses a system and a computer program method comprising instructions for enabling a computer to: acquire ultrasound image data for at least a portion of a body organ (Column 1, Lines 37-50; Column 2, Lines 25-38). *Clark* further discloses obtaining a 3D volume and displaying a plurality of views to a user which are automatically derived from the 3D data set (Column 3, Lines 35-47).

However, *Clark* is silent with respect to how the plurality of views are generated to define at least one other plane with respect to a reference plane for the body organ including spatial positions within the organ that define a relationship of the at least one other plane to the reference plane.

Cerqueira teaches an optimal approach for use in research and clinical patient management involving cardiac perfusion and function wherein at least one other plane is generated and defined with respect to a reference plane for the body organ which is based on specific data including spatial positions within the organ (Page 540 "Orientation of the Heart", "Recommendation", "Name for Cardiac Planes" and "Recommendation"). Examiner notes that by obtaining a "reference plane" (i.e. "apical 4-chamber echocardiographic view"), *Cerqueira* also approximates the horizontal long-axis view (i.e. "standardized plane").

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program as disclosed by *Clark* to generate and define at least one other imaging plane with respect to a reference plane as described by *Cerqueira* in order to accurately define and display other planes with respect to the reference plane in an acquired 3D volume to visualize views which cannot be directly imaged by 2-D imaging systems. Such a modification requires nothing more than the mere combination of known prior art techniques to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v.Teleflex Inc,* 82 USPQ2d 1385).

15. Claims 2-4 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Counsil on Clinical Cardiology of the American Heart Association" to *Cerqueira et al. "Cerqueira"* as applied to claim 1 above, and further in view of NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al. "Nelson".*

Regarding Claim 2, *Clark* in view of *Cerqueira* disclose a computer program product comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for an organ (heart) as described above.

However, *Clark* in view of *Cerqueira* do not expressly disclose wherein the body organ is a fetal heart.

Nelson discloses a system and a method implemented by a computer program product comprising instructions for enabling a computer to: acquire ultrasound data with a transducer for at least a portion of a body organ (fetal heart) (Page 1, "Introduction).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program as described by *Clark* in view of *Cerqueira* to be used to perform it on a fetal heart as described by *Nelson* in order to accurately visualize a vital organ of a fetus.

As for Claims 3-4, *Nelson* discloses a reference plane as the four-chamber view and wherein the at least one other plane comprises data defining a ductal arch view (Fig. 5)

As for Claims 18-20, *Nelson* also discloses generating and defining at least one other plane with respect to a reference plane for the body organ based on specific data including spatial positions within the organ that define a relationship of the at least one other plane to the reference plane (Pages 4-5, "Fetal Cardiac Data Visualization") and to display automatically and substantially simultaneously, at least two ultrasound images corresponding to at least of the reference plane and data defining the at least one other plane (Fig. 5). It should be noted that the generated planes are defined by a spatial mathematical

relationship which relate the planes to one another by either a shift or rotation from the reference plane (i.e. 90^{o}).

16. Claims 5-6 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Counsil on Clinical Cardiology of the American Heart Association" to *Cerqueira et al. "Cerqueira"* as applied to claim 1 above, and in further view of U.S. Patent No. 7,244,233 to *Krantz et al. "Krantz"*.

Regarding Claims 5-6 and 12, *Clark* in view of *Cerqueira* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for organs as described above. However, *Clark* in view of *Cerqueira* is silent with respect to the specific limitation of the organ being a fetal head. Further, *Clark* in view of *Cerqueira* is silent with respect acquiring ultrasound images for each of the sagittal, transverse, and coronal planes.

Krantz teaches from within the same field of endeavor with respect to ultrasound imaging of a fetus, a computerized method wherein the head of a fetus is imaged (Column 3, Line 62-Column 4, Line 5). Furthermore, *Krantz* teaches it is considered a well know expedient in the art to obtain ultrasound

images of the sagittal, transverse and coronal planes which would include the biparietal diameter (Column 10, Lines 26-36).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program instructions as disclosed by *Clark* in view of *Cerqueira* to acquire and display ultrasound fetal head images acquired in the sagittal, transverse and coronal planes as described by *Krantz* in order to enhance and detect of fetal abnormalities using ultrasound.

With regard to Claim 13, *Clark* discloses wherein the display is "real-time" (Column 2, Lines 21-23).

17. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Counsil on Clinical Cardiology of the American Heart Association" to *Cerqueira et al. "Cerqueira"* as applied to claim 1 above, and in view of in view of U.S. Patent No. 6,290,648 to *Kamiyama et al. "Kamiyama"* in further view of *Applicants Admission* of the prior art.

Regarding Claims 9-11, *Clark* in view of *Cerqueira* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. *Clark* in view of *Cerqueira* is silent with respect to a computer program comprising image

recognition software to facilitate the medical evaluation comprising steps to recognize a specific structure within an image, compare the structure with a reference image, and identify at least one of a normal and abnormal anatomical characteristic of the structure.

Kamiyama teaches an ultrasound diagnostic imaging apparatus (abstract) comprising image recognition software used to facilitate a medical evaluation (Column 7, Lines 58-67-Column 8, Lines 1-30). Furthermore, *Kamiyama* teaches wherein the software recognizes a specific structure within an image, compares the structure with a reference image, and identifies at least one of a normal and abnormal anatomical characteristic of the structure (Column 8, Lines 31-67).

Examiner further notes that Applicant has disclosed in the Specification, Paragraph [0067], "*One or more embodiments of the present invention can utilize, for example, standard (e.g. off-the-shelf) image recognition software to assess the level of the standardized planes and diagnose, or facilitate diagnosis…*". Examiner notes that an "off-the-shelf" program is considered to be well known and commercially available prior to the claimed invention. Therefore, one of ordinary skill in the art would readily recognize a modification to include well known computer software program as disclosed by Applicant and *Kamiyama* to evaluate acquired image data.

18. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation

and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Counsil on Clinical Cardiology of the American Heart Association" to *Cerqueira et al. "Cerqueira"* as applied to claim 1 above, and in view of in view of NPL "Sonography of the Normal Fetal Heart: A Practical Approach" to *Frates.*

Regarding Claim 21, *Clark* in view of *Cerqueira* discloses a computer program product comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. However, *Nelson* is silent with respect to obtaining image data corresponding to a number of gestational weeks. Examiner notes that it is considered a well known expedient in the art to correlate image acquisition of fetal organs with data such as gestational weeks as described by *Frates* (Fig. 11 A-D) since the fetus position changes during fetal development.

Response to Arguments

19. Applicant's arguments with respect to claims 1-7 and 9-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER COOK whose telephone number is (571)270-7373. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. C./
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737